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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/826,149

04/16/2004

Michael A. Spohn

CV/04-002

8770

21140

7590

11/14/2008

GREGORY L. BRADLEY

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EXAMINER

GILBERT, ANDREW M

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

11/14/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/826,149

**Applicant(s)**

SPOHN ET AL.

**Examiner**

ANDREW M. GILBERT

**Art Unit**

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 42, 55, 56, 58, 60, 70-73 and 75 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 42, 55, 56, 58, 60, 70-73 and 75 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/3/2008 has been entered.

### ***Acknowledgments***

1. This office action is in response to the reply filed on 9/3/2008.
2. In the reply the Applicant cancelled claims 27, 40, 41, 57, 59, and 74 and amended claims 42 and 60.
3. Thus, claims 42, 55-56, 58, 60, 70-73, 75 are pending for examination.

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 42, 57-60, 72-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trombley, III et al (6096011) in view of Morimoto et al (6224568) in further view of Genese (4243031). Trombley, III et al discloses an injector system comprising: a source of injection fluid (505); a pump device (350); a fluid path set (Fig

6A-B) disposed between the source of injection fluid and the pump device, and comprising a first section (420) and a second section (510); and at least one connector (Fig 2-5) providing the removable fluid communication between the first section and the second section, the connector comprising: a first connector member (155) associated with one of the first section and the second section and comprising an outer housing (172) and a first threaded member (172) disposed in the outer housing; and a second connector member (175) associated with the other of the first section and the second section and comprising a second threaded member (192); wherein the first threaded member and second threaded member cooperate to securely and releasably connect the first member to the second member to establish the removable fluid communication between the first section and the second section (Figs 1-6b; col 5, lns 38-45), and wherein the second threaded member is received in the outer housing of the first connector member when the first connector member is connected to the second connector member (Fig 5); as to claims 57-59 and 73-75, see (Fig 6A, B; wherein the drip chamber has a projection, or spike 520; 400; col 6, lns 18-34; and 194 and proximal edge portion of 155 (ie corners closest to reference number 166) in Fig 4).

6. However, Trombley, III et al does not expressly disclosing a connector having a first connector member having a first threaded member separated therefrom by an annular cavity.

7. Morimoto et al teaches that it is known to have a connector (13) having a first connector member (41) having a first threaded member (41, 43) separated therefrom by an annular cavity (41) for the purpose of providing a shield between the sealing

members (14, 41) of first and second connectors and the external environment helping to maintain sterility during storage or use. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the first connector as taught by Trombley, III et al with the first connector being separated therefrom by an annular cavity as taught by Morimoto et al for the purpose of providing a shield between the sealing members (14, 41) of first and second connectors and the external environment helping to maintain sterility during storage or use. Also, see discussion of Morimoto et al in Final Rejection mailed on 6/13/2008.

8. However, Trombley, III et al and Morimoto et al do not expressly disclose a second section having a pressure isolation mechanism having a lumen, a pressure isolation port, and a valve member biased to a normally open position permitting fluid communication between the lumen and the pressure isolation port and movable to a closed position when the fluid pressure in the lumen reaches a predetermined pressure level sufficient to overcome the biasing force of the biasing portion of the valve member.
9. Genese teaches that it is known to have a pressure isolation mechanism having a lumen, a pressure isolation port, and a valve member biased to a normally open position permitting fluid communication between the lumen and the pressure isolation port and movable to a closed position when the fluid pressure in the lumen reaches a predetermined pressure level sufficient to overcome the biasing force of the biasing portion of the valve member (Fig 4-5) for the purpose of having a pressure activated shut-off device for I.V. fluid administration to prevent damage to the device and patient in the advent of high pressure. It would have been obvious to one having ordinary skill

in the art at the time the invention was made to modify the second section as taught by Trombley, III et al and Morimoto et al with the pressure isolation mechanism as taught by Genese for the purpose of having a pressure activated shut-off device for I.V. fluid administration to prevent damage to the device and patient in the advent of high pressure.

10. Claims 55-56, and 70-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trombley, III et al in view of Morimoto et al in further view of Genese in final view of Raines et al (561268). Trombley, III et al and Morimoto et al disclose the invention substantially as claimed except for expressly disclosing a cap having a groove associated with a raised rib of at least one of the first and second connector members. Raines et al teaches that it is known to have a cap with a groove (21, 66, 16) for a connector member for the purpose of protecting the infusion port and connector prior to use. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as taught by Trombley, III et al and Morimoto et al with the protective cap as taught by Raines et al for the purpose of protecting the infusion port and connector prior to use.

### ***Response to Arguments***

1. Applicant's arguments with respect to claims 42, 55-56, 58, 60, 70-73, 75 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW M. GILBERT whose telephone number is (571)272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew M Gilbert/  
Examiner, Art Unit 3767  
/Kevin C. Simons/  
Supervisory Patent Examiner, Art Unit 3767